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Abstract

Our goal was to deliver a clinical solution to fluid resuscitation for combat casualties in the absence of advanced caregivers. We developed the Trauma Tablet Decision Support (DS), the first of a new breed of smart medical devices that provides caregivers with decision support using algorithms developed based on TCCC guidelines, expert opinion and resuscitation research. Trauma Tablet DS integrates a vital signs monitor, IV pump, and resuscitation algorithms controlled from a fat finger touch screen.

We submitted an application for an FDA 510K allowance of Trauma Tablet DS, which incorporated QNX OS, a military spec Panasonic Toughbook, an eQuality Criticare Monitor, and a Zoll IV Pump. The FDA response had addressable issues with the response being developed by Arcos, the licensee of this technology.

Trauma Tablet Closed Loop (CL) has been designed to provide automated titrated fluid therapy. The closed loop algorithms were developed and tested using the Impact LTM, and will be commercialized in the Trauma Tablet CL. The decision support and closed algorithms were tested in human subjects, and was shown to be robust and effective. Work effort on this project has transitioned from UTMB research and development to Arcos for advanced prototyping, regulatory approval, and commercialization, and to Dr. Mike Kinsky for clinical testing.

a. Scientific and Technical Objectives

Our research plan (from grant submission) called for the spiral development of a series of Resuscitation Systems. In brief:

1- A Resuscitation System that provides manual input of injury, physiological data and then provides *Decision-Assist* in the form of displays and specific directives.

Report Documentation Page

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1. REPORT DATE **21 FEB 2011**	2. REPORT TYPE	3. DATES COVERED **00-12-2005 to 00-09-2010**

4. TITLE AND SUBTITLE **Closed Loop Resuscitation Of Hemorrhagic Shock**	5a. CONTRACT NUMBER
	5b. GRANT NUMBER
	5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S)	5d. PROJECT NUMBER
	5e. TASK NUMBER
	5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) **University of Texas Medical Branch at Galveston,Sponsored Programs Academic,4.400J Rebecca Sealy Hospital,Galveston,TX,77555**	8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)	10. SPONSOR/MONITOR'S ACRONYM(S)
	11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Our goal was to deliver a clinical solution to fluid resuscitation for combat casualties in the absence of advanced caregivers. We developed the Trauma Tablet Decision Support (DS), the first of a new breed of smart medical devices that provides caregivers with decision support using algorithms developed based on TCCC guidelines, expert opinion and resuscitation research. Trauma Tablet DS integrates a vital signs monitor, IV pump, and resuscitation algorithms controlled from a fat finger touch screen. We submitted an application for an FDA 510K allowance of Trauma Tablet DS, which incorporated QNX OS, a military spec Panasonic Toughbook, an eQuality Criticare Monitor, and a Zoll IV Pump. The FDA response had addressable issues with the response being developed by Arcos, the licensee of this technology. Trauma Tablet Closed Loop (CL) has been designed to provide automated titrated fluid therapy. The closed loop algorithms were developed and tested using the Impact LTM, and will be commercialized in the Trauma Tablet CL. The decision support and closed algorithms were tested in human subjects, and was shown to be robust and effective. Work effort on this project has transitioned from UTMB research and development to Arcos for advanced prototyping, regulatory approval, and commercialization, and to Dr. Mike Kinsky for clinical testing.

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT **unclassified**	b. ABSTRACT **unclassified**	c. THIS PAGE **unclassified**	**Same as Report (SAR)**	**14**	

2- A semi-automatic Resuscitation System in which *Decision-Assist* recommendations, based on manual input from the caregiver and automated monitoring of physiological data, e.g. intermittent non-invasive measurements of blood pressure are provided.

3- A more advanced semi-automatic Resuscitation System that includes all of the features of Resuscitation System 2, but is also integrated with an IV fluid pump.

4- A fully automated *Close-Loop* Resuscitation System that has integrated monitoring technology interfaced with a microprocessor programmed with therapeutic algorithms. The algorithms control infusion rate and provide titrated infusion therapy based on minute-to-minute analysis of blood pressure.

b. Approach or Tasks

From original proposal - no change to original items 1-5. We added item 6 in 2008, and item 7 in 2009.

1) **Evaluate candidate BP monitors, sensors, infusion pumps** using bench-top testing, and experiments of hemorrhagic shock and resuscitation animal models. Select best candidate BP monitors and infusion pumps to move forward with additional testing and conceptual integration into Resuscitation Systems.

2) **Design, build and test data recorder software and Resuscitation-Displays** that show real-time data and time-course graphics of blood pressure and other primary and derived physiologic variables, as well as administered treatment (e.g. current and time-course of infusion rate and cumulative volumes).

3) **Perform evaluation of the accuracy, robustness, and user acceptance of selected BP monitors, displays and infusion pumps** in patients

4) **Design and test Decision-Assist recommendations and Closed-Loop controllers** in animal models.

5) **Demonstrate and Deliver to ONR** prototype Resuscitation-Systems

6) **Formalize strategies and a plan** for software validation and regulatory approval and best means for commercialization. Plan for decision assist and closed loop drug delivery Systems to integrate into a complete Automated Casualty Care System (ACCS).

7) **Deliver to FDA a 510K application** for the Decision Support Trauma Tablet.

c. Concise Summary

Spiral and evolutionary development was our approach. Our focus 1) resulted in a prototype Decision Support System and submission of a 510K application and Trauma Tablet; and 2) Planning integration of fluid and drug algorithms for the ACCS.

In the first years we evaluated several components for a DS and CL resuscitation system. We performed animal experiments on DS and CL fluid therapy. We prototyped devices testing several vital signs monitors (Athena WVSM; Philips MR2; Zoll Welch Allyn Propaq LT, and Propaq MD; and Criticare eQuality); development languages (C++; LabVIEW; and QNX); platforms (Touch Screen Tablets; PDA's; and ruggedized touch screen Laptops (Panasonic Touchbook); and operating systems (Windows and QNX RTOS); and IV pumps (Zoll Power Infuser, Gemini Delphi). We assessed other devices in development for integration (QRS BP Sure, Empirical Care Taker, Hutchinson InSpectra, Oridion Capno Stream). We collaborated

with Athena, Impact, Zoll, and BP Sure. The last 18 months had a focus on a commercial version DS platform that could be expanded to CL control of fluid therapy.

The Trauma Tablet Decision Support (DS) is a medical device that integrates four features: 1) A vital signs monitor (VSM); 2) A user interface, which provides input from the caregiver on specific questions of patient status; 3) Algorithms derived from ATLS and TCCC guidelines for recommended fluid therapy based on vital signs and caregiver input; and 4) An IV pump and controller to implement recommendations. The Trauma Tablet DS provides control of an IV pump via a titrated bolus algorithm. The VSM and Pump connections to the Trauma Tablet are wired.

We delivered a fully functional FDA ready Trauma Tablet DS incorporating the robust QNX and a fat finger touch screen running on a military spec Panasonic Toughbook interfaced with a eQuality Criticare Monitor and Zoll Power Infuser IV Pump. Software code verification is underway. We have performed extensive work with Athena WVSM and Impact LTM, and we await their FDA approval.

The Trauma Tablet was submitted to the FDA for 510K allowance. At the end of this grant Arcos received a reply from the FDA that suggested we have a reasonable pathway to approval. Arcos is working on a response.

d. Expanded Accomplishments
2006-08:

Prototypes: Our contract and purchase orders with InfoDat and Athena produced manual entry Trauma Tablet prototypes.

The PI and UTMB team designed and contracted with InfoDat, Inc. for the iterations of our first two Trauma Tablet's (TT) designed for a small Tablet PC (C code and LabVIEW, respectively). This TT-1 allowed manual input of a variety of variables including age, body weight, injury type, and severity. Physiological variables via electronic data capture are noninvasive blood pressure (NIBP), heart rate (HR), and modified Glasgow Coma score. The Trauma Tablet I provided *Decision Assist* for trauma associated with hemorrhagic hypovolemia and burn shock.

Proprietary screens display of Trauma Tablet were shown to program officer Mike Given. Detail on the version and specifications of the Trauma Tablet are found in our UTMB record-of-inventions.

Anesthetized animal studies were used to evaluate physiologic variable(s) to determine 1) Best means to assess the level of shock, and 2) if that endpoint can be used for an endpoint guide to resuscitation. We evaluated primary variables (blood pressure, pulse pressure, and heart rate), calculated indices (Shock Index) as well as more complex derived variables that require online computing. Ultimately for the current Trauma Tablet we used standard of care arterial blood pressure.

We collected data from hemorrhaged sheep experiments (funded by this ONR grant), and from a series of hemorrhaged, burn injured, resuscitated swine studies, and human volunteers subjected to experimental hemorrhage that are ongoing in our lab and funded by Shriners Burns Hospital and Dept of Anesthesiology. Additional data collection in these swine experiments did not interfere with the goals of our funded protocols.

We performed a series of hemorrhaged animal experiments with three goals: 1) test utility of

closed loop hardware; 2) assess accuracy of five advanced hemodynamic monitors; 3) collect data for advanced analysis of derived variables of hemodynamic monitoring including shock index, pulse pressure, pulse pressure index, systolic pressure variation, and heart rate variability.

<u>Data from Trauma Patients</u> were collected to determine the variables that are typically available and how often these variables are typically measured with standard of care. Research nurse and staff are on 24-hour call to attend major admits in the Emergency Department. Our team mostly collected data manually. In addition, the data was also sometimes captured automatically in memory modules. We collected hemodynamic, lactate, blood gas, and fluid balance data on trauma patients. We also collected data on burn patients over the first three days of in hospital ICU care with a focus on hourly urinary output and infused volume. These data were used to refine our resuscitation algorithms. The collected data was also used to evaluate relationships between fluid therapy and physiologic responses in trauma patients.

<u>Pumps</u>: We performed bench-top and animal studies of closed loop control using Zoll Power Infuser and the Delphi pump using the Trauma Tablet and the LTM, respectively. We made contact with Hospira and Fluid.Net, but there was no progress incorporating their COTS pump (Gemstar or FloNet).

<u>Wireless Vital Signs Monitor (WVSM)</u>: Note that NIBP, Pulse Ox, and ECG are the same non-invasively measured variables that the Athena Wireless Vital Signs Monitor (WVSM) provides. We received two WVSM's, and engineers at InfoDat and Wyle linked these WVSM's to prototype Resuscitation Systems (LTM software) and a Trauma Tablet prototype. The Trauma Tablet software continues to be refined, and some bugs in identified the WVSM are to be addressed by Athena.

<u>New IV Pump</u>: Our work on an IV pump of our design invention disclosure previously declared to ONR progressed. These recent pump efforts accomplished independent of this ONR project. A provisional patent application was filed, and a full application to be filed this year 2011.

<u>Blood Pressure Monitors</u>: An early goal was to identify the noninvasive blood pressure (NIBP) technologies that: 1) provide superior performance in noisy and vibration prone environments, and 2) can accurately measure blood pressures in a hypotensive range. We tested the QRS BPCard technology, and have contracted for two BPSure monitors with new motion tolerance that was modified in order to communicate with the Trauma Tablet. We first tested and funded QRS and then BP Sure for motion tolerant prototypes. The BP Sure technology had promise, but we have halted further funding due to corporate reorganization, and a loss of our confidence that progress will be made. We ran tests on the Emperical -NIBP beat-to-beat finger cuff Care Taker. Motion tolerance was demonstrated, and accuracy will be assessed in Dr. Kinsky's human testing ONR grant. We also are acquiring a variety of other commercial NIBP monitors that purport to have high accuracy, and motion tolerance including the WVSM-BP and LTM NIBP systems. We are evaluating these devices in human volunteers, and with a blood pressure simulator in both a quiet environment and in moving vehicles.

<u>Lightweight Trauma Module (LTM) Interface</u>: Wyle Laboratories provided under contract PO a prototype Specialized Resuscitation System (LTM-Platform) that incorporated our initial resuscitation algorithms. This allowed us to collect data and compare multiple NIBP as well other sensors including Pulse ox, ECG in our animal studies. Two algorithms for controlling infusion have been programmed into the prototype LTM. Experiments were completed that demonstrated the ability to restore and maintain blood pressure during multiple hemorrhages using a modified Delphi IVantage pump. We continued to use the SRS as our test platform for closed loop experiments.

Algorithms: In our previous ONR grant, which focused on titrated resuscitation in animal studies, we developed several robust algorithms. These algorithms proved their resilience when blood pressure was continuously measured and animals were subjected to controlled hemorrhage and volume replacement. Based on our clinical analysis we know that blood pressure measurements will be sporadic. For this reason the algorithms we previously used are not fully applicable in initial field and emergency department resuscitation efforts and will require a new approach to algorithm development. We have designed these algorithms and have started their testing.

2008-09:

Program officer Mike Given reviewed the RTOS Trauma Tablet and with existing and future screens display during a June 2009 site visit. Detail on this version and specifications of the Trauma Tablet are in our record of inventions with a patent application filed August 2009. Our first automated pressurized infuser prototype (UTMB) was also demonstrated and discussed at the site visit.

Wireless Vital Signs Monitor (WVSM): We continue our close collaboration with Co-I Mike Kinsky on this grant as well as his grant on clinical testing of Decision Assist and closed loop technologies. Our efforts were leveraged by our 2008-2012 NIH grant on closed loop resuscitation of burn injury and a 2009-2011 grant from the Moody Brain Injury foundation on closed loop treatment of brain injury and two grants from Athena GTX.

The Trauma Tablet software continues to be refined and some bugs in the WVSM were identified and addressed by Athena. Also, note that our work on an IV pump of our design continues. Our pump invention disclosure was previously declared to ONR. These recent pump efforts were accomplished independent of ONR funding. A new provisional application will be filed on the pump technology.

Continuous Noninvasive Blood Pressure Monitoring: We have run tests on the Empirical -NIBP beat-to-beat finger cuff care taker. Caretaker technical problems continued, and at this time we cannot provide a definitive report on its utility.

Lightweight Trauma Module (LTM) Interface: Wyle Laboratories has provided under a contracted PO a prototype, Specialized Resuscitation System (LTM-Platform). Impact also provided a LTM without a ventilator. We embedded our initial resuscitation algorithms, and collected data in these platforms. The prototype LTM is programmed with two closed loop algorithms for controlling infusion. Animal experiments demonstrated the ability to restore, and maintain blood pressure during multiple hemorrhages using a modified Delphi IVantage pump, and the Zoll power infuser. We continued the SRS as our test platform for closed loop experiments, and have now tested it with a Zoll pump.

Progress 2008-09 Numbered Objectives:

1) We continued refining user interface, resuscitation displays and functionality of the Trauma Tablets. Trauma Tablets 2 thru 4 are functional, and are undergoing continued refinement.

2) We developed a new anesthetized animal model of multi-hemorrhage requiring damage control surgery, and postsurgical care that provides a unique testing platform for the Trauma Tablet, and other related CCC technologies [3] (Research costs were shared with Athena and Moody Brain Injury Foundation).

3) We evaluated the NIBP Care Taker believing that a beat-to-beat motion tolerance device capable of measuring low pressure with tachycardia is key to optimized early fluid therapy. In brief, results have been poor. Caretaker prototypes have not functioned well. Technology is still very much in development phase. This evaluation is preliminary.

4) We produced plans to interface the Trauma Tablet with other COTS devices, and emerging sensor, and pump technologies. This is not yet been accomplished.

6) We performed studies of real time multivariable analysis of traditional, and new vital signs, predictive variables and other indices to provide early warning of the need for fluid volume, and for its titrated delivery. [4-6]

7) We continued to evaluate small IV fluid pumps in closed-loop mode. We also will support some testing of the UTMB pump developed out of this ONR funding. We leveraged our ONR funding with a Technology Ignition fund grant from the University of Texas System.

8) We continued to evaluate approaches to potentially proprietary data verification, noise reduction, redundancy strategies, and any method that improves accuracy and motion tolerance. Recent data analysis from our animal experiments suggests powerful and sensitive multivariable indices for degree of hypovolemia/cardiovascular state can be developed. This work is ongoing, and is the focus of engineering graduate student Ben Voigt.

9) We continued close collaborations with the Institute of Surgical Research on nearly all aspects of our research.

10) We continued to work with Galveston startup Resuscitation Solutions, Inc., Athena GTX, and Impact Instrumentation on the commercialization of the algorithms, indices, and the integration of our autonomous resuscitation system.

We published two peer-reviewed manuscripts on decision support and closed loop fluid therapy for treating hemorrhagic shock [1] and burns [2].

2009-10:

We maintain close communication with Dr. Mike Given. The PI George Kramer, Co-I Mike Kinsky and chief project engineer Chris Meador with two trips this past year to ONR CCC, Arlington. Proprietary RTOS Trauma Tablet and with existing and future screens displays were shown to and discussed with program officer Mike Given, Bill Sobotka and CDR Tim Coakly. A Technology Transfer Agreement between ONR and Arcos provided the draft range of specifications for a Closed Loop Fluid Delivery System to be delivered with FDA application in FY13.

<u>Trauma Tablet Prototype:</u>

The improvements to the Trauma Tablet prototype fall into two broad categories: hardware and software. The first hardware improvement was to transition from a 6-pin to a 12-pin connection from the Hub Control (computer controller) to the pump. The 12-pin connection allows us to verify the pump's actual speed when sending it an activation command, and allowed us to detect when the pump is disconnected versus alarming (the alarms are digital outputs; with the 6-pin connector we only saw "0" volts, which could have been an alarm or absence of connection).

The second major hardware improvement was with the Vital Signs Monitor. We originally planned to use the Athena Wireless Vital Signs Monitor (WVSM). We received the "FDA ready" Athena WVSM prototype in June 2009, and were able to demonstrate its basic functionality with the Trauma Tablet. However, there are a few design aspects, which have not been implemented, and the Athena GTX WVSM has not yet received FDA 510(k) clearance. In order to continue progress on our project we needed to find an alternative VSM. We hope to use the Athena GTX WVSM in the future.

We surveyed many VSMs to find one that fit the needs of this project (small, light-weight, portable), and with which we could successful communicate. By the end of May 2010, we had thoroughly tested, and are very pleased with the robust wired communication link between the Criticare eQuality monitor and our Hub Control. The Criticare eQuality also has blue-tooth capability, but we have not yet tested its wireless communication.
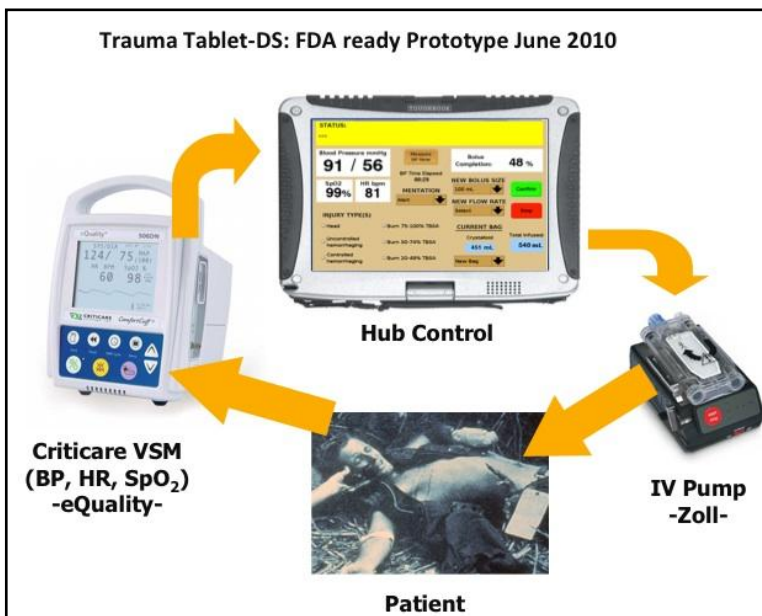
There have been a number of software improvements during this year. We have included new features in our working prototype, including: bolus and flow-rate selections, total infused fluid volume indicator, a fluid bag indicator to calculate and alert the user when the fluid bag needs changing, and allowing multiple injury type selections. One of the main FDA concerns with software in medical devices is usability, so we have put a lot of attention into ease of use and simplicity of the Graphical User Interface (GUI). In June 2009, our proprietary GUI looked as such:

By the end of May 2010, we consolidated indicators, simplified the user interface, increased button sizes for ease of use, increased font sizes for better view ability, and several other changes to produce the following GUI. The GUI was approaching its final form.

The prototype at the end of May 2010 is pictorially shown here:

Trauma Tablet-DS: FDA ready Prototype June 2010

Hub Control

Criticare VSM
(BP, HR, SpO$_2$)
-eQuality-

IV Pump
-Zoll-

Patient

Animal studies funded by a different grant provided the data we continued to use to evaluate physiologic variable(s) to evaluate a variety of noninvasive, and invasive vital signs, predictive indices, and hemodynamic variables for assessment of the level of hypovolemia. Specifically, we compared traditional vital signs (blood pressure, pulse pressure and heart rate), calculated indices (several shock indices) as well as more complex derived variables that require online computing or new technology (pulse pressure variability, pulse wave transit time, stroke volume, tissue O$_2$), and central venous O$_2$. Muscle tissue oxygen saturation (Hutchinson Inspectra) measured using noninvasive near infrared spectrometry (NIRS) provided the highest specificity and sensitivity that a hemorrhage was occurring.

Continuous Blood Pressure Monitoring: We performed pilot testing on the Empirical -NIBP beat-to-beat finger cuff Care Taker, and the Nexfin technologies. Both work, but their range of effectiveness and limitation for monitoring hypotensive shock remain to be determined. The Nexfin works in both humans (finger), and pigs (tail). This provides the opportunity to perform testing in reproducible animal models. CareTaker will have to be tested in patients due to its use of calibrated pressure waves. We believe that incorporating continuous blood pressure into future decision support and automated critical care systems is key to developing algorithms for fluids and drugs delivery as part of the ACCS.

Algorithm incorporation in integrated critical care systems: We modified the LTM prototype to operate a Zoll Power Infuser, and added a closed loop algorithm to control the infusion pump. This closed loop prototype uses real time arterial pressure to continuously adjust infusion rate using a nonlinear algorithm of our design. The system has been tested in animals and in human volunteers with Dr. Kinsky's ONR grant. This shows the feasibility of exporting the fluid therapy algorithms to systems such as the LTM and MOVES.

Novel IV pump: We supported testing of the UTMB rapid infuser pump invention that developed out of this ONR grant. A Technology Ignition Fund (TIF) grant from the University of Texas System allowed us to build a prototype bolus rapid infuser that was used in our titrated bolus animal studies.

Sharing of Algorithms: Per our correspondence, and discussions at ATACCC, I have provided our developed algorithms to commercialization companies Athena and Impact to use in the WVSM and LTM, and we are working to test them using their technology in our animal studies. We continue to develop modified algorithms that should be applicable, and that will be tested in

our upcoming animal experiments.

Leveraging Efforts: We continued close collaborations with the US Army Institute of Surgical Research on nearly all aspects of our research on this project on fluid resuscitation of hemorrhage, fluid resuscitation of burns, and novel monitoring approaches. Our efforts continue to be leveraged by a 2008-2012 NIH grant on closed loop resuscitation of burn injury; a 2009-2011 grant from the Moody Center on Brain and Spinal Cord Injury and closed loop treatment of brain injury; a 2008-present grant from Athena GTX; and a 2009-2010 Technology Ignition Fund (TIF) University of Texas System grant for construction of a pump prototype. We maintain communication with Impact and Athena on how our research, development, and technologies can provide synergism to deliver the best products for combat casualty care. We received funding for a 3-year Army grant focused on the development of titrated boluses therapy at three centers (UTMB-ICU, ISR-ICU, and UT Houston-ED). This grant will leverage our clinical testing of new algorithms and resuscitation concepts.

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Navarro LHC, Lima RM, Kinsky MP, Voigt RB, Sondeen J, Dubick M, Salinas J, <u>Kramer GC</u>: Assessment of vital signs and hemodynamic variable for evaluation of blood loss. In: *Proceedings of the 2009 Annual Meeting of the American Society Anesthesiologists: October 17-21, 2009; New Orleans, LA*.

Patents

George C. Kramer, Guy Drew, Donald Deyo, Allen E. Brandenburg: System And Method For Fluid Infusion And Balance Monitoring. In 2010 U.S. Patent Application.

g. Technology Transfer

Patents-Inventions: A patent application on the Trauma Tablet was planned, but remains to be filed. Recent novel and useful features have been added to the invention including new copyrighted displays and algorithms. In particular, engineering graduate student Ben Voigt, working with postdoctoral fellow Dr. Lima and the PI developed a predictive adaptive algorithm for closed decision support with novel resuscitation displays.

Our first automated pressurized infuser prototype (UTMB) was demonstrated and discussed at the ONR site visit. A provisional patent application was applied for the pump in December 2009, and full USPTO application in December 2010.

Our efforts resulted in the founding of Arcos Medical that will commercialize the decision support and closed loop fluid delivery technologies. The PI and Contract Engineer Chris Meador are company principals. Arcos licensed the UTMB Trauma Tablet Technology and the US Army/UTMB's burn decision support and closed loop fluid therapy.

Licensing of the UTMB pump technologies is ongoing, and anticipates completion in the next 12 months. It may be licensed to RSI. The PI is a principal of RSI.

h. Foreign Collaborations and Supported Foreign Nationals
Rodrigo Lima, MD, and Lais Navarro, MD, PhD Brazilian citizens and funded in part form July 2008 thru May 2010.

Thank you: The PI would like to thank ONR for the last 9 years of basic and applied research on titrated fluid therapy of hypovolemic shock. This grant was instrumental in not only the Trauma Tablet and automated fluid delivery system research described above, but was also seed for the development of burn decision support system that is now practice of care at the US Army Burn Center, and UTMB. We are productizing the Burn Decision Support technology for US Army deployment; and the Closed Loop Resuscitation continues under development at UTMB and ISR. The PI is handing off to Arcos for final productization, and Mike Kinsky for any clinical work needed.

Although this grant moved to the productization of a dedicated smart fluid therapy system there are the next steps needed to optimize the increasingly complex en route care system. This grant has produced preliminary data for several basic and applied studies needed to support the future Automated Critical Care System. Three areas of research and development that are needed include: 1) technology demonstration of continuous non-invasive blood pressure for decision support, and closed loop control to include prototyping, and studies using both animals and humans; 2) development of decision support and automated control algorithms for drug delivery; 3) independent clinical assessment of new vital signs, predictive variables, and their incorporation into decision support and automated systems for fluid and drug delivery.

Tasks completed 2009-10

> **Task 1   Prototype delivery**
> Deliver a FDA ready decision support Trauma Tablet to ONR for evaluation. Scheduled for August 31, 2010.

> **Task 2   Submit 510K application**
> A 510k application on the decision support Trauma Tablet scheduled for September 30, 2010

Task 3   <u>Automated Fluid Therapy Prototype:</u>
Produce a prototype Trauma Tablet that will also run in closed loop mode. This is scheduled for September 30, 2010.

f. not needed
Major Problems/Issues

Major Problems

1) Despite grant approval before end of FY09 the funding did not arrive until 6.5 months into FY10. We received a notice around that time that we were at risk of losing funding and we were behind on our FY10 spend plan. The PI refrains from providing his views on this.

2) The failure of Athena to receive FDA approval of the WVSM was a major blow as per ONR's Dr. Given this was the vital signs monitor of preference. However, we identified another small vital signs eQuality Criticore that met all requirements for data capture and remote control of NIBP. We have evaluated the Propaq M and the Phillips MR2 vital signs monitors, but at present they will not allow remote control of NIBP. These monitors can only be implemented by providing a command for the caregiver to initiate a BP measurement, which is a one-button push on the VS monitor. While this is a solution, it is not ideal.